Clean copy of the allowed claims

1. A system for clinical trial simulation, comprising:

an interface having a fixed form module and a trial definition language free form module, the interface configured to receive information that describes a trial protocol comprising a plurality of schedules for a clinical trial simulation and to receive information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

a translator having a protocol parser and a code generator, the protocol parser configured to parse the trial protocol, the code generator configured to generate source code in a high level general purpose programming language;

a compiler having a code parser and a machine code generator, the compiler configured to compile the generated source code into an executable program comprising a plurality of programmable state machines, each state machine corresponding to one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression; and

a controller communicatively coupled with the interface, the translator, and the compiler, the controller configured to run the executable program including the plurality of programmable state machines, according to a time queue.

2. The system of claim 1, wherein the fixed form module is configured to receive trial protocol information conforming to a structured format.

3. The system of claim 2, wherein the free form module is configured to receive trial protocol information in a trial design language, conforming to a predefined structured language format designed for clinical trial simulation.

5. The system of claim 1, wherein the plurality of schedules comprises a dosing schedule.

6. The system of claim 1, wherein the plurality of schedules comprises an observation schedule.

9. A method for clinical trial simulation, comprising:

receiving trial protocol information that describes a clinical trial simulation in a fixed form and a trial definition language free form;

receiving information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

arranging the trial protocol information into a plurality of schedules;

translating the plurality of schedules into a high level general purpose programming language;

compiling the translated plurality of schedules into an executable program comprising a plurality of state machines, each state machine corresponding to one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and

schedule parameters in response to information generated in simulation based on the disease progression; and

executing the program including the plurality of state machines, according to a time queue as part of the clinical trial simulation.

10. The method Of claim 9, wherein the receiving step comprises:

receiving trial protocol information that conforms to a structured format; and

receiving trial protocol information in a trial design language, conforming to a predefined structured language format designed for clinical trial simulation.

11. The method of claim 9, wherein the plurality of schedules comprises a dosing schedule.

12. The method of claim 9, wherein the plurality of schedules comprises an observation schedule.

14. A computer readable medium having stored thereon one or more sequences of instructions for causing one or more microprocessors to perform the steps for simulating a clinical trial, the steps comprising:

receiving trial protocol information that describes a clinical trial simulation in a fixed form and a trial definition language free form;

receiving information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

arranging the trial protocol information into a plurality of schedules;

translating the plurality of schedules into a high level general purpose programming language;

compiling the translated plurality of schedules into an executable program comprising a plurality of state machines, each state machine corresponding to one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression; and

executing the program as part of the clinical trial simulation including the plurality of state machines, according to a time queue.

15. The computer readable medium of claim 14, wherein the receiving step comprises:

receiving trial protocol information that conforms to a structured format; and

receiving trial protocol information in a trial design language, conforming to a predefined structured language format designed for clinical trial simulation.

16. The computer readable medium of claim 14, wherein the plurality of schedules comprises a dosing schedule.

17. The computer readable medium of claim 14, wherein the plurality of schedules comprises an observation schedule.

19. A system comprising a microprocessor, a persistent storage area, a volatile storage area and a communication means, the system including an execution area configured to simulate a clinical trial by performing the following steps:

receiving trial protocol information that describes a clinical trial simulation in a fixed form and a trial definition language free form;

receiving information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

managing the trial protocol information into a plurality of schedules, the plurality of schedules comprising a dosing schedule and an observation schedule;

translating each of the plurality of schedules into a high level general purpose programming language;

compiling the translated schedules into an executable program, comprising a plurality of programmable state machines, each state machine corresponding to a discrete one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression; and

executing the program as part of the clinical trial simulation including the plurality of state machines, according to a time queue.

20. The system of claim 1 wherein the translator operates according to a syntax and a structure of the trial protocol.

21. The system of claim 20 wherein the protocol parser is configured to determine a syntax and a structure of the trial protocol, to convert the trial protocol into an intermediate format, and to pass the intermediate format to the code generator.

22. The method of claim 9 wherein the trial protocol information is arranged into a plurality of schedules according to a syntax and a structure of the trial protocol information.

23. The method of claim 22 wherein the trial protocol information is analyzed to determine the syntax and structure.

24. The method of claim 14 wherein the trial protocol information is arranged into a plurality of schedules according to a syntax and a structure of the trial protocol information.

25. The method of claim 24 wherein the trial protocol information is analyzed to determine the syntax and structure.